

REMARKS

Claims 163, 164, and 166-186 are cancelled. Claims 160 and 165 are amended. New claims 187-190 have been added. Claims 160-162, 165, and 187-190 are now pending. Reconsideration is respectfully requested in view of the following remarks.

I. Claim Rejections Under 35 U.S.C. 112, First Paragraph

The Examiner rejected claims 160-165 under 35 U.S.C. 112, first paragraph, for scope of enablement. The Examiner asserts that “the specification while being enabling for treatment of bronchoconstriction, lung inflammation, lung allergy, or asthma by administering the composition herein, dose not reasonably provide enablement for the **prophylaxis** of bronchoconstriction, lung inflammation, lung allergy, or asthma employing the composition in claim 160, and “prevent or counter” in claim 165.” *See* Office Action, at 5.

While Applicant disagrees with the Examiner’s position, but in the interest of expediting prosecution of the application, Applicant has amended claims 160 and 165 to remove the terms “prophylaxis” and “prevent, counter.” Applicant believes that this rejection is now moot and respectfully requests its withdrawal.

II. Claim Rejections Under 35 U.S.C. 112, Second Paragraph:

The Examiner rejected claim 165 under 35 U.S.C. 102, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In particular, the Examiner states that the recitation “the subject’s tissue” “renders the claim indefinite. *See* Office Action, at 9. Applicant has amended claim 165 to delete this term. Based on this amendment, Applicant respectfully requests the withdrawal of this rejection.

III. Claim Rejections Under 35 U.S.C. 103(a):

The Examiner rejected claims 160-164 under 35 U.S.C. 103(a) as being unpatentable over Pendergast (4,956,355) in view of Lieberman et al. (Pharmaceutical Dosage Forms, page 110).

Also, the Examiner has rejected claims 160 and 165 under 35 U.S.C. 103(a) as being unpatentable over Nyce (5,527,789) and Lieberman et al. (Pharmaceutical Dosage Forms, page 110).

The Examiner has acknowledged that Pendergast “does not expressly disclose the particular range of respirable particle size herein.” *See* Office Action, at 9. Further, the Examiner states that Nyce “does not expressly disclose the particular particles of active agents having respirable size herein.” *See* Office Action, at 11. The Examiner asserts that Lieberman et al. “teaches that a skilled artisan in pharmaceutical science would clearly know that the granulation, determination of size, or size reduction of a solid pharmaceutical formulation, e.g., in nasal formulation, have several benefits” *See* Office Action, at 9, emphasis added. However, the Lieberman et al. reference cited by the Examiner makes no reference to nasal formulation and addresses “Size reduction, as it applies to tablet production ...” (Emphasis added).

Applicant has amended claim 160 to recite “particles of less than about 5 μm in size.” Further, new claim 187 recites “particles about 0.5 μm to about 10 μm in size or 10 μm to 500 μm in size.” The Examiner acknowledges these particle sizes are not taught by Pendergast and Nyce. Further, these particle sizes are not taught by Lieberman et al. as this reference is directed to “tablet formula development” and not nasal or inhalable formulations. Hence, Applicant respectfully requests the withdrawal of this rejection.

IV. Double Patenting:

The Examiner has rejected claim 165 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-19 of U.S. Patent No. 5,527,789.

Claim 165 depends from claim 160 which has been amended to recite “particles of less than about 5 μm in size.” Claims 13-19 of U.S. Patent No. 5,527,789 do not include the particle size limitations. Hence, Applicant respectfully requests the withdrawal of this rejection.

Application No. 10/072,010
Amendment dated September 9, 2004
Reply to Office Action of March 9, 2004

CONCLUSION

In light of the remarks set forth above, Applicants believe that they are entitled to a letters patent. Applicants respectfully solicit the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any question, the Examiner is encouraged to telephone the undersigned.

Respectfully submitted,

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